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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION

CENTOCOR ORTHO BIOTECH, INC. ,

Plaintiff,

v.

GENENTECH, INC. and CITY OF HOPE,

Defendants.

AND RELATED COUNTER AND THIRD-PARTY AFFILIATES

Case No. CV 08-03573 MRP (JEMx)

The Honorable Mariana R. Pfaelzer

CENTOCOR ORTHO BIOTECH, INC.'S AND ITS COUNTER-DEFENDANT AFFILIATES' REPLY IN SUPPORT OF THEIR MOTION FOR CONSTRUCTION OF CLAIM TERM "IMMUNOGLOBULIN" (MOTION NO. 2)

Date: August 17, 2010
Time: 11:00 a.m.

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I. SUMMARY OF ARGUMENT IN REPLY

There is a meaningful dispute regarding the proper construction of "immunoglobulin molecule." Defendants argue that the PTO did not rely on its construction of that term in deciding to issue the reexamination certificate, but the prosecution history belies that argument. At the very least, it should be left to the *jury* to decide whether the PTO's actions were premised on a faulty claim construction. Centocor is entitled to make that argument, but can do so only if the Court rules on the proper construction of "immunoglobulin molecule."

The Cabilly II Patent provides an express definition of "immunoglobulin" which was never disclaimed or disavowed. The definition encompasses both functional and non-functional molecules, and it is that legally correct definition which Centocor asks the Court to adopt.

II. "IMMUNOGLOBULIN MOLECULE" REQUIRES CONSTRUCTION

A. The Prosecution History Evidences that the Construction of "Immunoglobulin Molecule" Was Important to the PTO's Decision to Issue the Reexamination Certificate

In an attempt to avoid having the Court rule on the proper construction of "immunoglobulin molecule" ("Ig molecule"), Defendants argue that it is just not necessary to do so because we should take its word for the fact that the PTO did not rely on the definition of that term in deciding to reverse two and a half years' worth of rejections of the Cabilly II Patent claims. But that is an issue for the jury to decide, not an issue to be decided in pre-trial motions. We cannot bring the patent examiners to trial to explain their thinking; all we have is the written record.

The written record, as well as the testimony of Genentech's reexamination counsel, reveals that the PTO's understanding of the construction of "Ig molecule" was important to its reasoning in issuing the reexamination certificate. Otherwise, why was the definition of that term mentioned not only in the PTO's Notice of Intent to Issue Reexamination Certificate ("NIRC"), but also in the PTO's summary of the *ex parte*

interview that shortly preceded issuance of the NIRC? (*See*, pages 2-3 of Centocor's Opening Brief; Pearson Decl. Exs. 13 and 14). Indeed, with respect to asserted Claim 33, the *only thing* mentioned in the PTO's summary of that important interview was the discussion of the meaning of the term "immunoglobulin molecule" and the conclusion that "'immunoglobulin molecule' is considered to be an immunologically functional immunoglobulin molecule" (Pearson Decl. Ex. 13 at GENE-CEN 022347).

Genentech mistakenly argues that the PTO made no reference to the "immunologically functional" limitation in distinguishing the prior art. But that argument is directly contradicted by these statements in the NIRC:

> Upon reconsideration of the declarations by Harris, McKnight, Botchan, Colman, and Rice, a person of ordinary skill in the art at the time the invention was made would not have had a reasonable expectation of success modifying the Cabilly I Patent claims in accordance to the teachings of Axel, Rice, Kaplan, Builder, Accolla, Dallas, Moore patent, Deacon and Valle, and Ochi references of record to produce an *immunologically functional* immunoglobulin molecule by independently expressing immunoglobulin heavy chain and light chain in a single transformed host cell.

(Pearson Decl. Ex. 14 at GENE-CEN 022454, emphasis added).

> The combination of the Cabilly I patent claims and the teachings of Axel, Rice, Kaplan, Builder, Accolla, Dallas, Moore patent, Deacon and Valle and Ochi references do not suggest or contain an enabling disclosure of a method to produce an *immunologically functional* immunoglobulin molecule by independently expressing immunoglobulin heavy chain and light chain in a single transformed host cell.

(*Id.* at GENE-CEN 022455, emphasis added).

When one considers the prosecution history record just preceding the February 2009 interview and issuance of the NIRC, it is not surprising that the PTO examiners focused in on whether "Ig molecule" was limited to "immunologically functional" molecules. Genentech had filed its appeal brief in December 2008 (Pearson Decl. Ex. 37). In that brief, Genentech's counsel emphasized that the Cabilly II inventors contended that successful production of a *functional* multimeric protein was part of an allegedly pioneering advance:

> The inventors' work was the first report of a host cell that had been genetically engineered to produce two different desired eukaryotic polypeptides in a single host cell. It also was the first report of the successful recombinant production of a *functional* multimeric protein having the structural complexity of an immunoglobulin. The Cabilly inventors' approach in each case sharply diverged from the conventional thinking in the field.
>
> * * *
>
> In reality, the '415 invention and its proof of successful production of a *functional* antibody both revolutionized and surprised the industry.

(*Id*. at GENE-CEN 020118-19 (emphasis added)).

Moreover, Genentech emphasized in its appeal brief evidence of alleged commercial success, which, it argued, supported the conclusion that the Cabilly II Patent claims were nonobvious (*Id.* at GENE-CEN 020179-80). Genentech referred to the Declaration of Dr. Fintan Walton in which he discussed the royalty revenue paid to Genentech for numerous *therapeutic antibody products* sold in the United States (Pearson 2d Decl. Ex. 53 at GENE-CEN 021423-32). Therapeutic antibody products are, of course, immunologically functional. But since it is hornbook law that evidence of commercial success must be commensurate in scope with the scope of the invention, the PTO should have considered whether Dr. Walton's evidence was commensurate in scope with the scope of the Cabilly II Patent claims. If those claims cover Ig molecules which are *not* immunologically functional (as Centocor contends they do), then Dr. Walton's evidence (accepted on its face for the sake of argument) would necessarily fall short. *In re Kulling*, 897 F.2d 1147, 1149 (Fed. Cir. 1990) ("objective evidence of nonobviousness must be commensurate in scope with the claims") (quoting *In re Lindner*, 457 F.2d 506, 508 (C.C.P.A. 1972); *In re Hiniker Co*., 150 F.3d 1362, 1369 (Fed. Cir. 1998) (evidence of secondary considerations of nonobviousness unpersuasive where not commensurate with the claim scope); *In re Tiffin*, 448 F.2d 791, 792 (C.C.P.A. 1971) (evidence of commercial success and satisfaction of long-felt need with respect to

"cups" not commensurate with the scope of claims broadly reciting "containers"); *Therasense, Inc. v. Becton, Dickinson and Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010) ("Because the claims are broad enough to cover devices that either do or do not solve the 'short fill' problem, [patentee's] objective evidence of non-obviousness fails because it is not 'commensurate in scope with the claims which the evidence is offered to support'") (internal citations omitted); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 n.4 (Fed. Cir. 2008) (claims which are broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter). Thus, there were multiple reasons why the scope of the claim term "Ig molecule" should have been relevant to the PTO's patentability determination.

Much of Genentech's brief is taken up with technical arguments for why – despite the clear indications in the record to the contrary – the PTO, allegedly, really could not have relied on its faulty construction of "Ig molecule" in changing its mind about the validity of the Cabilly II patent claims. Genentech can make those arguments to the jury, just as Centocor can point to contrary arguments and evidence, much of which is outlined above. But the import of the PTO's construction of "Ig molecule" is an issue to be resolved by the jury, and that can only happen if the issue of the scope of the term "Ig molecule" is resolved.

Notably absent from Genentech's opposition is any representation that it will refrain from trying to convince the jury that the validity of the Cabilly II patent claims was signed, sealed and delivered with issuance of the Reexamination Certificate. That proposition, of course, is legally wrong, as the validity of the claims will be determined by this Court and/or by the jury. *See*, e.g., *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1366-67 (Fed. Cir. 2007) (court finds clear and convincing evidence of obviousness even though prior art considered during reexamination). But to counter Genentech's inevitable arguments about the importance of the reexamination,

Centocor must have the ability to point to all deficiencies in the PTO's reasoning, including its legally erroneous construction of "Ig molecule."

But even if Genentech were to agree not to tout the reexamination result as having decided validity issues, it would still be necessary to construe "Ig molecule" because Genentech intends to introduce, through the same Dr. Walton who provided a declaration in the reexamination, evidence of alleged commercial success of the Cabilly II claims based on licensing revenues received for sales of *functional* antibodies. If the claims encompass both functional and non-functional Ig molecules – as Centocor contends they do – then Dr. Walton's evidence of commercial success is not commensurate in scope with the claims, and there will be an issue as to whether it should even be admitted.

For all of these reasons, the Court's construction of "Ig molecule" is needed and is respectfully requested.

III. CENTOCOR'S CONSTRUCTION IS CORRECT

Genentech invites legal error by proposing that the Court ignore the explicit definition of "immunoglobulin" in the Cabilly II specification in favor of a definition Genentech allegedly "agreed to" in the interference. That argument fails on several levels.

A. The Patent's Express Definition is Controlling

Genentech erroneously suggests that Centocor propounds that "Ig molecule" must include non-functional Igs merely because the Cabilly II specification discloses non-functional Igs ("NSIs") (Def.'s Br. at 14). But that is not the case. The Cabilly II specification does more than just disclose non-functional Igs. It expressly *defines* "immunoglobulin" as including both functional and non-functional molecules:

> [I]mmunoglobulins refers to such assemblies *whether or not specific immunoreactive activity is a property*.

(Pearson Decl. Ex. 20 at 6:3-11, emphasis added). When, as here, a patent applicant has elected to be a lexicographer by providing an explicit definition for a claim term, the definition selected by the patent applicant controls. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc) ("Our cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."); *Sinorgchem Co. v. U.S. Int'l Trade Comm'n*, 511 F.3d 1132, 1138 (Fed. Cir. 2007) ("When the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term") (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998).

Genentech concedes that the Cabilly II specification "defines an 'immunoglobulin' to include antibodies, which are functional in that they bind antigen, and non-specific immunoglobulins, which are not," but seems to suggest that "immunoglobulin" should take its meaning from the Boss specification from which Claim 33 was copied (Def.'s Br. at 2). But what the Boss specification may or may not say about "immunoglobulins" is irrelevant to the construction of that term in the Cabilly II patent claims. Those claims must be construed based on the specification in which they appear – the Cabilly II specification. *Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1997) (claims copied from another patent are interpreted in light of the specification in which they appear). And the Cabilly II specification expressly defines "immunoglobulin" consistently with Centocor's proposed construction.

B. Genentech's "Agreement" or Subjective Understanding is Irrelevant

Genentech's or the PTO's subjective understanding, or wishful thinking, regarding the meaning of the "Ig molecule" cannot trump the express definition in the Cabilly II specification. *Akamai Techs., Inc. v. Cable & Wireless Internet Services*, 344 F.3d 1186, 1194 (Fed. Cir. 2003) ("what the patentee subjectively intended his claims to

mean is largely irrelevant to the claim's objective meaning and scope") (quoting *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000); *Bell Atlantic Network Services, Inc., v. Covad Commc'ns Group, Inc*., 262 F.3d 1258, 1273 (examiner's statement of Reasons for Allowance will not necessarily limit a claim).

Despite Genentech's attempt to cast it as such (Def.'s Br. at 14), the issue here is not whether Genentech disclaimed or disavowed claim scope by purportedly "agreeing" to the PTO's proposed construction of "Ig molecule." Rather, the issue is whether the express definition of "immunoglobulin" provided in the Cabilly II specification can be trumped by an applicant's – or even an examiner's – "understanding" or "agreement" as to the meaning of the term. It cannot. *Phillips*, 415 F.3d at 1315 (specification is "single best guide" to the meaning of a disputed term); *Boss Control, Inc. v. Bombardier Inc*., 410 F.3d 1372, 1378 (Fed. Cir. 2005) ("while it is true that during prosecution the applicants twice used the phrase 'cut off' interchangeably with the term 'interrupt,' this usage does not operate to erase the clear definition of 'interrupt' found in the specification"); *Eastman Kodak Co. v. Goodyear Tire & Rubber Co*., 114 F.3d 1547, 1556 (Fed. Cir. 1997) ("To the extent that the examiner's certificate purports to ascribe meaning not found in the claim language, this court must not permit prosecution history evidence to 'enlarge, diminish, or vary' the meaning of claim language"); *SRAM Corp. v. AD-II Engg., Inc*., 465 F.3d 1351, 1359 (Fed. Cir. 2006) (court not bound to PTO's flawed claim constructing made during reexamination). The cases Genentech cites, *ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075 (Fed. Cir. 2003) and *TorPharm, Inc. v. Ranbax Pharm., Inc.*, 336 F.3d 1322 (Fed. Cir. 2003) (Def.'s Br. at 14), are inapposite because they do not address the situation, as here, where the specification contains an express definition of a claim term.

C. Genentech Improperly Seeks to Rewrite the Claim With Its Proposed Construction

Genentech's argument that it would be "strained" to read Claim 33 – which recites a method for producing "an Ig molecule or an immunologically functional Ig

fragment"– to cover functional *and* non-functional Ig molecules on the one hand, but only functional Ig fragments, on the other (Def.'s Br. at 13 n.3), is without merit. Strained or not, that is the way Genentech drafted the claim, and the plain language of the claim makes a distinction between Ig molecules (which are not limited to functional molecules) and Ig fragments (which are so limited). Precedent does not permit the Court to essentially redraft the claim so that it comports with Genentech's concept of what makes sense. *Chef America, Inc. v. Lamb-Weston, Inc*., 358 F.3d 1371, 1373-74 (Fed. Cir. 2004) (claims required heating dough "to" 400 to 850 degrees; court will not read "to" as "at," even though baking dough to those temperatures burns it "to a crisp").

IV. CONCLUSION

For the reasons presented above and in Centocor's opening brief, Centocor respectfully requests an order construing "immunoglobulin molecule" and "immunoglobulin" as:

> A tetrameric molecule consisting of two longer polypeptide chains called heavy chains and two shorter [polypeptide] chains called light chains, or aggregates of such tetrameric molecules, whether or not specific immunoreactive activity is a property.

Dated: August 3, 2010

AKIN GUMP STRAUSS HAUER & FELD LLP

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PROOF OF SERVICE

I, Matthew A. Pearson, the undersigned, certify and declare that I am over the age of 18 years, employed in the County of Philadelphia, State of Pennsylvania, and not a party to the above-entitled cause. My business address is Akin Gump Strauss Hauer & Feld LLP, 2001 Market Street, Suite 4100, Two Commerce Square, Philadelphia, Pennsylvania 19103.

On August 3, I served a true and correct copy of the following document described as:

CENTOCOR ORTHO BIOTECH, INC.'S AND ITS COUNTER-DEFENDANT AFFILIATES' REPLY IN SUPPORT OF THEIR MOTION FOR CONSTRUCTION OF CLAIM TERM "IMMUNOGLOBULIN" (MOTION NO. 2)

on the interested parties in this action as follows:

[ ] **By Federal Express**: By placing the document(s) listed above in a sealed overnight courier envelope addressed as set forth below and routing the envelope for pick up with Federal Express for overnight delivery.

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[X] **By Email**: I caused the document(s) to be sent to the person(s) at the email addresses set forth below and/or based on General Order 08-02, the attached document was sent through the Court's Electronic Filing System (ECF).

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